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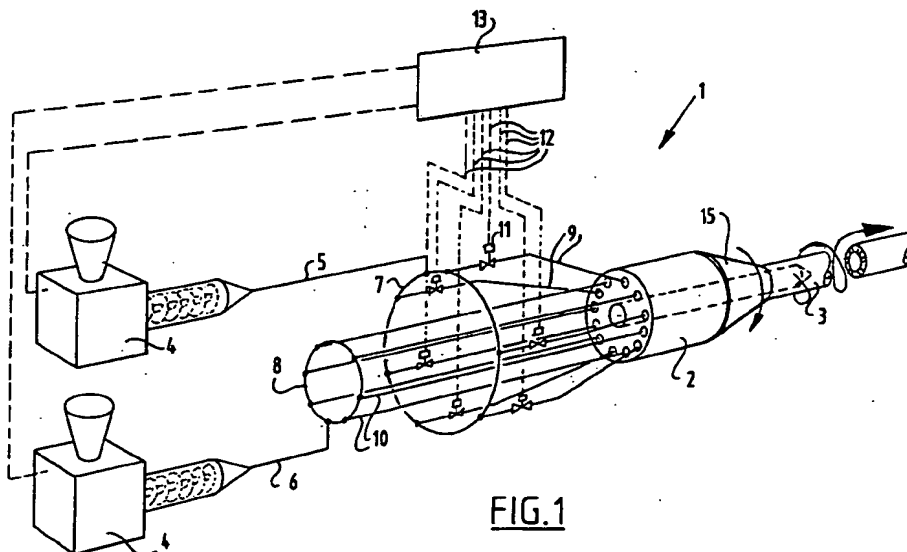
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**NL-2517 GK Den Haag (NL)**(54) **Method for manufacturing a tube-like extrusion profile and a catheter made in accordance with this method.**

(57) The invention relates to a method for manufacturing a tube-like extrusion profile (3). The method comprises simultaneously conveying a number of, in the circumferential direction of the profile divided streams of material of at least two different compositions to a moulding-nozzle (2) and making the streams flow together in the moulding-nozzle (2). At

least one of the streams is supplied rotating in a circumferential direction. The method also comprises allowing the combined stream of material to cool off into the extrusion profile so that the stream of material supplied in a rotating manner extends helically in the extrusion profile (3).

**FIG.1****EP 0 662 385 A1****BEST AVAILABLE COPY**

The invention relates to a method for manufacturing a tube-like extrusion profile with a desired combination of properties, in particular with regard to flexibility, torsional stiffness and pressure resistance.

Catheters used for angiographic purposes for instance comprise a tube-like basic body which must have a good torsional stiffness in order to be able to manipulate the catheter properly. Furthermore, this material should have a high compression resistance to allow for example the introduction of contrast medium under high pressure via the catheter.

The usual catheters of this type therefore comprise a braided reinforcing layer of metal wire, providing the required properties.

With the continuing trend towards ever thinner catheters it is becoming increasingly difficult and expensive to manufacture a suitable tube-like basic material in this way.

The object of the invention is therefore to provide a method for manufacturing a tube-like extrusion profile with a desired combination of the above-mentioned properties.

This aim is achieved with the method as characterised in claim 1. The helically shaped band of material formed in the extrusion profile can for instance be made of a stiffer material than the basic material, so that a good compression resistance and reliable torsional stiffness can be achieved. Furthermore a very good torsional stiffness in both directions can be obtained, which for an intended application as basic material for a catheter is most desirable.

With the special embodiment of the method as characterised in claim 2 a reticulated pattern of bands of material in the basic material is obtained. Thus a great flexibility can be combined with a high torsional stiffness.

An advantageous embodiment is characterised in claim 3. Each of the obtained helically shaped bands of material extends uninterrupted but, because of the combined effect of the helically shaped bands of material in the different layers, a good torsional stiffness and compression resistance is nevertheless obtained.

By employing the measure as set out in claim 4 the relation between the torsional stiffness and bending stiffness can be varied. In general a large pitch of the helical line results in a lower torsional stiffness but a higher bending stiffness and vice versa. Furthermore, a tube-like extrusion profile with a large pitch of the helically shaped bands of material extends less easily in a longitudinal direction.

In general the distal end of a catheter should be very pliable to prevent trauma. Additional increase in or reduction of the pliability can be

achieved by employing the method as claimed in claim 5.

To enhance the properties of the material of the streams of material added in a rotating manner, the measure as set out in claim 7 can be employed. Doing so, the modulus of elasticity can be increased significantly.

The invention relates to and also provides a catheter made of a tube-like extrusion profile according to the invention, comprising at least one section of which the wall comprises helically shaped bands of material of varying composition.

The invention will be explained in greater detail in the following description with reference to the attached drawings.

Fig. 1 shows in a general way a method for manufacturing a tube-like extrusion profile.

Fig. 2 illustrates an extrusion profile manufactured by this method.

Fig. 3 shows an embodiment of the method according to the invention.

Fig. 4 shows an extrusion profile manufactured by another embodiment of the method.

Fig. 1 shows schematically an extrusion device which can be used to carry out the method of the invention. This device 1 comprises a moulding-nozzle 2, inside of which the extrusion profile 3 is formed. The embodiment of the method as described here involves the use of streams of material of two different compositions. Each of the materials is brought in an extruder 4 in the for extrusion required correct degree of liquidity and at the right pressure. The material coming from the first extruder 4 is conveyed, through a line 5, to a distribution line 7. From this distribution line a number of lines 9 branch off, each of which can convey a stream of material.

The second extruder 4 leads to a line 6 also connected to a distribution line 8 which, in its turn, links up with a number of lines 10 conveying separate streams of material.

As fig. 1 shows there are in this embodiment twelve, in the circumferential direction of the tube-like profile 3 distributed streams of material of two different compositions. The different materials can be incorporated in a pattern of alternate bands in the wall of the profile 3.

The streams of material conveyed through the lines 9 and 10 flow together in the moulding-nozzle 2. This moulding-nozzle 2 comprises a schematically indicated rotating section 15 through which the streams of material are supplied rotating in a circumferential direction. After allowing the combined stream of material to cool off in the usual manner, the extrusion profile 3, comprising bands of material extending in a helical pattern, has been formed. The extrusion profile formed will be explained in greater detail below, with reference to

fig. 2.

In each of the lines 9, conveying the streams of material of the first composition, cut-off valves 11 have been arranged. Each of these cut-off valves 11 can be controlled by means of control lines 12 by a control means 13. The control means 13 can open or close the cut-off valves 11 during the extrusion process in a controlled manner and consequently the streams of material conveyed through the corresponding lines 9 can be turned on and off in a similar controlled manner. The control means 13 can be made to control the extruders 4 as well. The opening and closing of the cut-off valves 11 is preferably programmed in a preset cycle. Manual operation is obviously possible as well.

In the embodiment as shown in fig. 1 the streams of material through the lines 10 are conveyed continuously and those through the lines 9 can be turned on and off in a controlled manner by the cut-off valves 11.

Fig. 2 shows, somewhat simplified, the extrusion profile obtained. As the streams of material are supplied in a rotating manner, the helically shaped bands of material 18 mentioned before, are formed in the extrusion profile 3. These have been incorporated in a basic material 19. For the sake of clarity only four helically shaped bands of material have been drawn in fig. 2, whilst six of them are formed with the set up as shown in fig. 1.

In fig. 2 it has also been indicated schematically, that by altering the relation between the rotation velocity and the extrusion velocity, a variation in the pitch in the longitudinal direction of the profile can be arranged. In the part 22 drawn on the right-hand side, no rotation has been applied and consequently the streams of material extend parallel to the longitudinal direction. In the adjacent part 21 a rotation has been applied at a limited velocity, so that a relatively small pitch of the helically shaped bands is obtained. The section 20 on the left, has been formed at a relatively high rotation velocity, resulting in a large pitch angle.

In case the helically shaped bands of material 18 are made of a stiffer material than the basic material 19, the part 20 of the extrusion profile formed, will have a relatively high torsional stiffness and low bending stiffness, while the section 22 will have a relatively high bending stiffness and low torsion rigidity. By varying the above-mentioned relation between the rotation velocity and extrusion velocity, the properties of the extrusion profile can be adjusted.

In addition to adjusting the properties of the extrusion profile by varying the angle of the helical line, the properties can also be varied of course by controlling the supply of the different streams of material as described.

Fig. 3 illustrates an embodiment of the method according to the invention. In this case two streams of material are supplied rotating in opposite directions. This has been indicated with two rotating parts 26,27 of the extrusion nozzle. The at least two streams of material are supplied rotating alternately to and fro at such an angle that the streams of material touch each other. With the profile 25 of fig. 3 a relative rotation of 90° occurs. With the reversal of motion the two parts of the extrusion nozzle remain stationary for a short period, and the two streams of material from the different nozzles mix, resulting in the reticulated pattern of the interconnected helically shaped streams of material as illustrated in fig. 3. If the material 28 of the helically shaped bands of material is stiffer than the basic material 29, the extrusion profile 25 thus obtained will display a good torsional stiffness combined with a reasonable pliability. The pressure resistance will be excellent.

The extrusion profile 30 shown in fig. 4 can be obtained with an embodiment of the method according to the invention developed to a greater degree.

The extrusion profile 30 is made up of two coaxial layers 31,32. In each of the layers 31,32 a number of helically shaped bands of material have been extruded. The helically shaped bands of material 33 in the outermost layer 31 are running in the opposite direction to the helically shaped bands of material 34 in the inmost layer 32 of the extrusion profile. The two layers with the helically shaped layers of material formed inside, can be manufactured in one extrusion movement. In that case a good bond between the inner layer and the outer layer can be simply ensured by a choice of the right combination of materials of the two coaxial layers.

By an alternative method it is also possible however to manufacture the inside layer 32 first and to arrange the outer layer 31 around it subsequently, for instance by extruding the latter onto the inner layer 32.

As fig. 4 illustrates, the pitch of the helically shaped bands of material varies in the longitudinal direction of the extrusion profile. This variation has been effected in the manner described above by varying the relation between the rotation velocity and the extrusion velocity.

By varying the pitch of the different layers of material in the way described, if desired in combination with selectively turning on and off a number of streams of material, a great variety in properties along the length of the piece of extrusion profile can be obtained. Because of this the entire length of the tube-like basic body of a catheter, for instance a catheter used for angiographic purposes, can be manufactured in one go. Separately

fixing pliable distal end sections or compression resistant proximal end sections respectively, has therefore become superfluous.

Although in each of the figures a number of helically shaped layers of material are shown, the invention can of course also be employed with one single helically shaped band of material.

The material for the profile is chosen in accordance with the intended application. In this way one can choose, when manufacturing an extrusion profile for a catheter as mentioned before, a soft polyurethane, polyethylene, polyamide etc. as basic material and a stiff plastic material from the same group for the helically shaped bands of material. One can also add a fibrous material, for instance aramide fibres or liquid crystal polymers, to the material used for the helically shaped bands. This will increase the modulus of elasticity of this material significantly.

It will be clear that through flow control of the streams of material the bands of material, which are referred to as the helically shaped bands of material in the above, will gradually take on certain proportions, such that it would be better to call these the basic material. For the method according to the invention there is therefore no essential difference between the basic material and the helically shaped bands of material when a single helically shaped band is employed.

#### Claims

1. Method for manufacturing a tube-like extrusion profile, comprising simultaneously conveying a number of, in the circumferential direction of the profile divided streams of material of at least two different compositions to a moulding-nozzle and making the streams flow together in the moulding-nozzle whereby at least two streams of material are supplied in circumferential direction rotating in opposite directions, and allowing the combined stream of material to cool off into the extrusion profile so that at least two helically shaped bands of material extend in opposite directions in the extrusion profile.
2. Method according to claim 1, wherein the at least two streams of material are supplied rotating alternately to and fro at such an angle that the streams of material at least touch each other.
3. Method according to claim 1, wherein the at least two streams of material supplied in a rotating manner are supplied at different diameters.
4. Method according to one of the previous claims, wherein the relation between the rotation velocity and the extrusion velocity is varied in the longitudinal direction of the profile for at least one of the streams of material supplied in a rotating manner, so that the consequently helically shaped stream of material in the extrusion profile has a varying pitch.
5. Method according to one of the previous claims, wherein at least one of the streams of material is turned on and/or off in a controlled manner during the extrusion.
6. Method according to one of the previous claims, wherein a soft plastic material from the polyurethane, polyethylene or polyamide, etc. group is chosen as basic material and a hard plastic material from the same group for the material supplied as a rotating stream.
7. Method according to claim 6, wherein fibres are added to the material supplied as a rotating stream.
8. Method according to claim 7, wherein the fibres are chosen from the group of aramide fibres and liquid crystal polymers.
9. Catheter with a tube-like extrusion profile manufactured by the method according to any of the preceding claims containing at least one section, the wall of which consists of helically shaped bands of material of different composition.

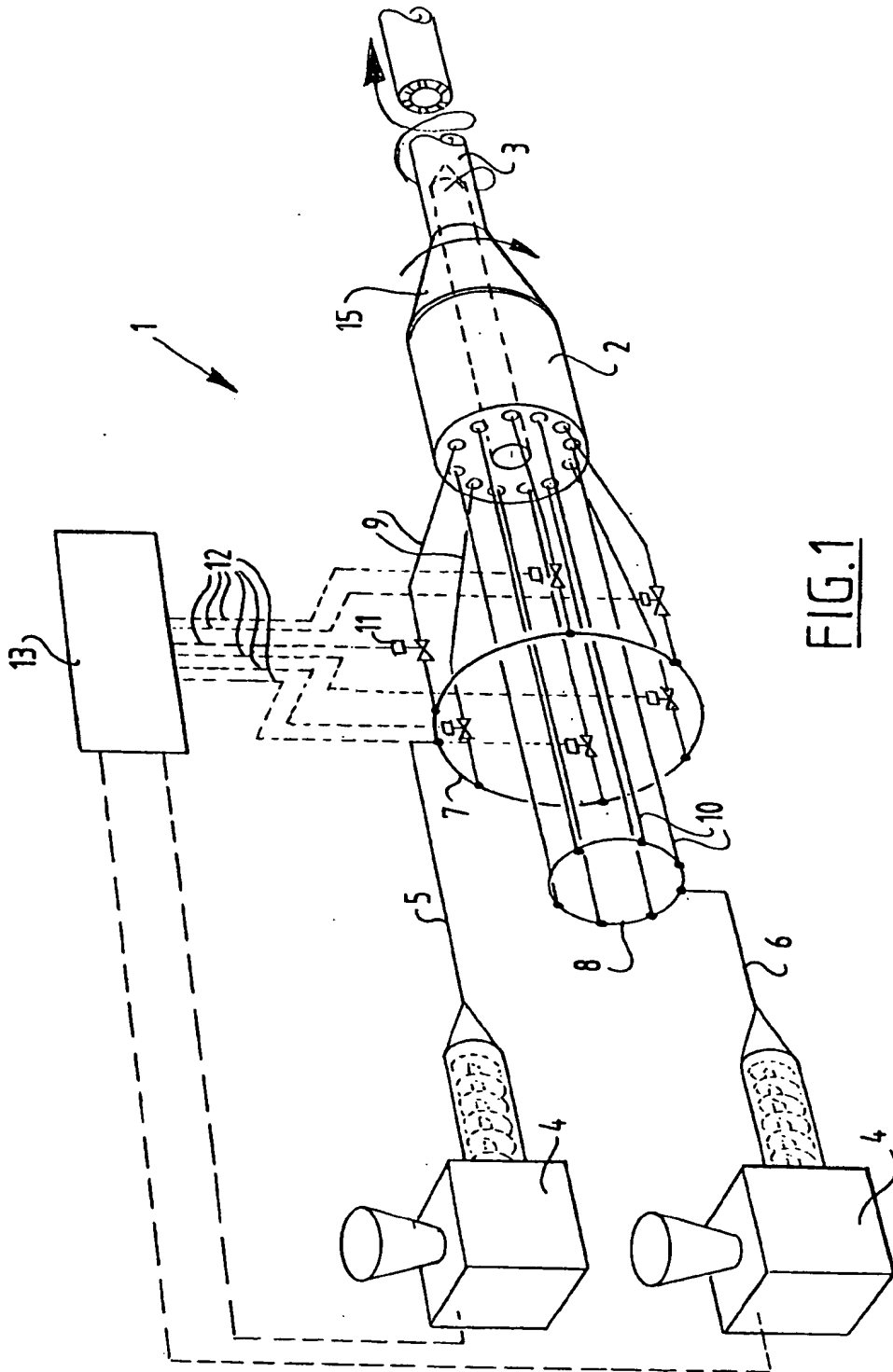
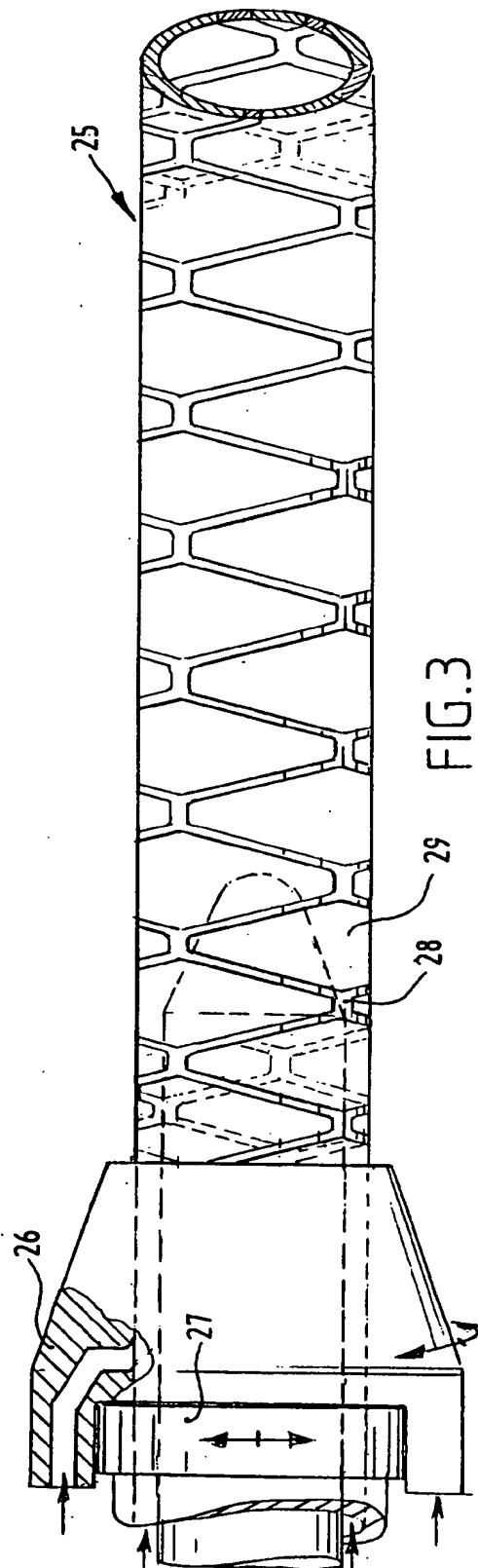
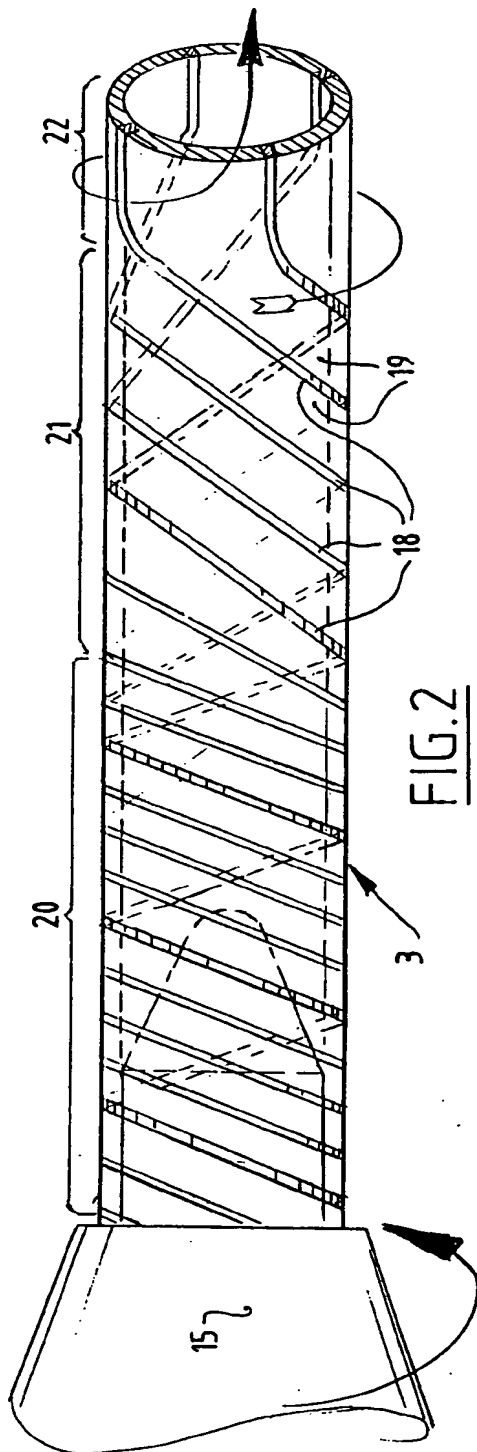


FIG. 1



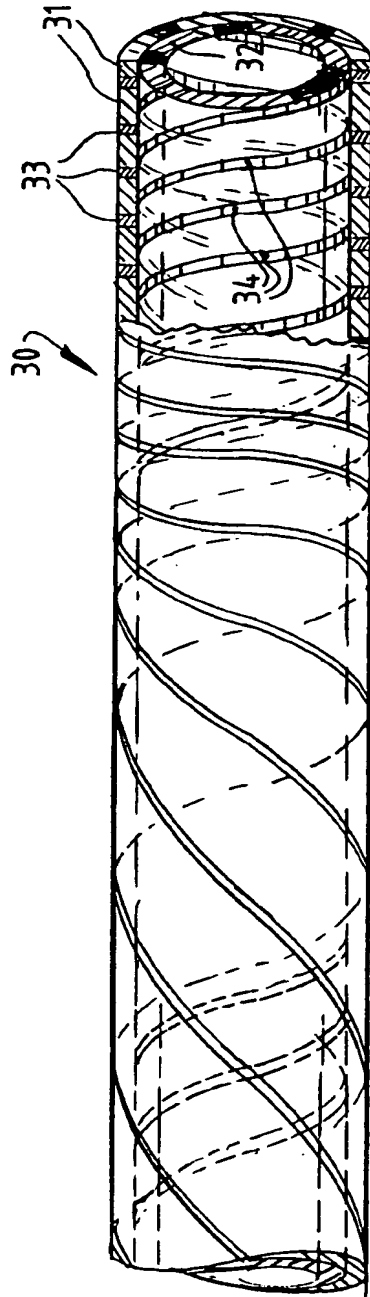


FIG. 4



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## EUROPEAN SEARCH REPORT

Application Number  
EP 94 20 3715

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	CH-A-279 074 (DÄTWYLER AG) * page 3, left column, line 28 - line 43; figures 1,2 * * page 3, right column, line 77 - page 4, left column, line 7; figures 5-9 * ---	1,6	B29C47/04 B29C47/24
A	US-A-2 779 970 (R. STÖCKER) * column 2, line 64 - line 71; figures 1,4 * ---	1,6	
A	US-A-3 606 636 (H.L. GLASS ET AL.) * column 7, line 23 - line 36; figure 7 * ---	1,4,6	
A	GB-A-1 349 843 (CREATORS LTD.) * page 2, left column, line 2 - line 35; figures * ---	1,3,4,6	
A	DE-A-19 38 720 (K. KALWAR) * page 3, paragraph 2; figure 7 * * page 4, paragraph 2 - paragraph 3; figures 8,9 * ---	3	
A	FR-A-1 555 590 (M. LABARRE ET AL.) * claim 1; figure 6 * ---	1,2	TECHNICAL FIELDS SEARCHED (Int.Cl.6) B29C
A	FR-A-2 649 641 (B.F. FIGUERO) * page 5, column 8 - line 16; figures 1,2 * ---	7,8	
A	US-A-4 276 250 (F.E. SATCHELL ET AL.) * column 1, line 16 - line 24 * * column 4, line 22 - line 26; figure 1 * * column 4, line 49 - line 56 * ---	1,5,9	
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The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 7 April 1995	Examiner Jensen, K
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DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US-A-3 752 617 (N.W. BURLIS ET AL.) * column 4, line 12 - line 59; figures 1,2,9 * * column 5, line 50 - column 6, line 3; figure 8 * -----	1,5,9	
			TECHNICAL FIELDS SEARCHED (Int.Cl.6)
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 7 April 1995	Examiner Jensen, K
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